First thoughts...

In the not-so-distant past, healthcare research mostly tended to involve large, academic-led studies, but times are definitely changing – as highlighted by a recurring theme of patient participation that runs through this issue of the Noclorn newsletter.

It’s very encouraging that the NHS Long-Term Plan (Page 3) aims to increase the number of people registering to participate in health research to one million by 2023/24. It’s the critical importance of research and innovation in driving medical advances that has been recognised in the NHS Long-Term Plan, with a commitment to enhancing the benefits these bring to both patients and the UK economy.

Under the 10-year plan, announced in January this year, research investment is set to double for the period 2015 to 2020, with £300 million of government support. Patients benefit enormously from research and innovation, with breakthroughs enabling prevention of ill-health, earlier diagnosis, more effective treatments, better outcomes, and faster recovery. Research and innovation are also important for the UK economy, bringing jobs and innovation in driving medical advances.

The critical importance of research and innovation in driving medical advances has been recognised in the NHS Long-Term Plan, with a commitment to enhancing the benefits these bring to both patients and the UK economy.

The UK has a worldwide reputation for the quality of the research conducted here. The HRA has an important role to play in protecting and advancing that reputation, ensuring that regulation governing research in the UK is appreciated and understood, and works for all our stakeholders.

Research wins critical acclaim in NHS 10-year plan

Growing concerns about the mental health of young people have made the NHS’s target of increasing participation of teenagers and young adults in clinical trials to 50% by 2025, with £2.3 billion allocated to improve access to talking therapies for 350,000 children and young people, as well as 380,000 adults.

And finally, Brexit is a subject impossible to ignore at the moment. Research and innovation in driving medical advances has been recognised in the NHS Long-Term Plan, with a commitment to enhancing the benefits these bring to both patients and the UK economy.

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A recurring theme of patient participation runs through this issue of the newsletter

– Lynis Lewis, Service Director, Noclorn Research Support

“A recurring theme of patient participation runs through this issue of the newsletter”

Visit our website: http://www.noclorn.nhs.uk or follow us on Twitter @NoclornResearch for more news and details of how we support one million of government support. Patients benefit enormously from research and innovation, with breakthroughs enabling prevention of ill-health, earlier diagnosis, more effective treatments, better outcomes, and faster recovery. Research and innovation are also important for the UK economy, bringing jobs and services.

Along with measures to prevent 150,000 heart attacks, strokes and dementia cases, the aim is to increase the number of people registering to participate in health research to one million by 2023/24. People will be able to view opportunities to participate and register interest on the NHS App by 2020.

Teresa Allen, chief executive of the Health Research Authority, said: “It is encouraging to see the plan aligns with our ongoing areas of focus such as linking and correlating genomics and clinical and patient data. The UK has a worldwide reputation for the quality of the research conducted here. The HRA has an important role to play in protecting and advancing that reputation, ensuring that regulation governing research in the UK is appreciated and understood, and works for all our stakeholders.”

Making research everybody’s business

Professor of Sexual and Reproductive Health at UCL, Professor Nick Lemoine of the NIHR Clinical Research Network, shows how research in future issues of the newsletter.

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is spreading further and wider into the “Cinderella” areas of healthcare. And finally Brexit is a subject impossible to ignore at the moment. Professor Martin McKee (Page 12), professor of European public health at the London School of Hygiene and Tropical Medicine, advises to the EC on health and a member of Scientists for EU, shares his fears about the damaging impact that leaving the EU will have on NHS research.

“Cinderella” areas of healthcare.

Dr Anita Lim (Page 11), professor of European public health at the London School of Hygiene and Tropical Medicine, advises to the EC on health and is a member of Scientists for EU, shares his fears about the damaging impact that leaving the EU will have on NHS research.

Professor of Sexual and Reproductive Health at UCL, Professor Nick Lemoine of the NIHR Clinical Research Network, shows how research is spreading further and wider into the “Cinderella” areas of healthcare. And finally Brexit is a subject impossible to ignore at the moment.
In the previous incarnations of the Clinical Research Network, there was always a strong topic-specific focus, typically in the acute hospital sector. There was a cancer network, a diabetes network, and a medicines for children network – and then there was the comprehensive research network, which covered everything else.

In the previous incarnations of the Clinical Research Network, on the challenge of spreading out to areas of healthcare that have historically been neglected, there was always strong research focus blossoming in new areas. There was a cancer network, a diabetes network, and a medicines for children network. It was interesting to see the challenges we used to face; how we would work with the same population for research in a number of different disciplines.

We organised the medical directorate by grouping specialties in clusters with obvious links, such as diabetes, cardiovascular disease, and stroke, and maternal health with children’s health; and clusters that involve specialties with less obvious links, such as mental health, public health and health services research. Moulding the groupings was one of the attractions of the job. Although many of our specialty leads in the medical directorate are doctors, we recognise that this might not be the optimum situation. That means we have to be slicker about how we assess the feasibility of a study in the NHS, who it needs to be done by. So we’ve been looking at the impact and implications of this for the network.

For the network and, over time, we’ve seen a broadening in terms of where research is going to change the nature of the research we do, who we do it with, and what it needs to be done by. So we’ve been looking at the impact and implications of this for the network.

An example is stratified, or precision, medicine. In 2014, the average size of a cohort for a typical clinical trial was 160 patients; now it is fewer than 100, because we’re selecting on the basis of particular characteristics.

That means we have to be slicker about how we assess the feasibility of a study in the NHS, such as how we select sites and how we train our workforce. It’s an important insight into research in the future.

We’ve also been looking at advanced imaging, what kind of imaging gets included in our portfolio to new areas means that we need specialist intelligence and support from a range of clinical investigators. One of our specialty cluster leads is a professor in pharmacy, for instance, and it would be difficult for the directorate being perceived as an exclusive club for doctors.

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The funding for the network has essentially been flat cash for the last eight years. With inflation, this means we actually had a net decrease in the amount of resources available. Recruitment has gone up, but we’ve now reached the absolute limit of value-for-money savings. To maintain current performance on a shrinking revenue base is going to be a big challenge.

Making research everybody’s business

interpreting innovations in clinical trials for hard-to-reach or historically under-represented groups. Anecdotally we know that older patients have less access to clinical research than younger ones. And there are geographical differences in research into particular diseases, such as lung cancer. Although 75% of the burden of chronic lung cancer is in the north of England, 75% of the research is conducted in the south.

We want to balance that inequity through the investigator community, and across the wider NHS. By engaging researchers think more imaginatively about where they conduct their research to benefit patients.

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Broad is a great risk for the stability of medical research. Already some European consortia have decided not to go ahead with UK partners—for instance, on rare diseases—and this is a very worrying trend.

Any interruptions in the medical supply chain will also affect our ability to deliver clinical studies. Medical and clinical research in the UK is going to be in for a bumpy ride, for a while at least. Alongside my work at NIHR, I’m also working simultaneously, and we’ll need more organic, with multiple specialisms provision for individuals will need to be shift to reflect that. Healthcare in the future healthcare environment in the future was designed to help lay clustering of some of our specialities historical speciality boundaries, and the questions about issues that will cross multiple morbidities, or co-occurring tension about how that’s achieved.

Current resource outside the NHS into other for the benefit of the UK and its population. Yet there are important questions to be asked don’t really have an investigator community, and social care environments. Care, we’re expected to conduct research in become the Department of Health and Social Sciences academies for conducting clinical research.

It’s a work in progress and I think the healthcare, in the UK is going to be in for a bumpy ride, for a while at least. The other challenging issue is multiple morbidities, or co-occurring diseases. We need to ask research questions about issues that will cross historical specialty boundaries, and the clustering of some of our specialties was designed to help the groundwork for that. It’s a work in progress and I think the healthcare environment in the future will shift to reflect that. Healthcare provision for individuals will need to be not really have an investigator community, with multiple specialties working simultaneously, and we’ll need to do research in that environment.

Shared ambition puts patients in forefront of studies

Giving more patients the opportunity to participate in clinical studies of health enriching the studies to the patients—and that is exactly what the new clinical directors of North Thames Clinical Research Network (CRN) are aiming to do. Professors David Wheeler and Margaret Johnson took up their positions last November as a job share, having previously worked together at the Royal Free NHS Foundation Trust for 15 years. The National Institute of Health Research has extended CRN contracts until 2022. As NIHR national specialty leader for renal disorders, Wheeler-less director of the Barts Cancer Institute at Queen Mary University of London and director of R&D for cancer and surgery for Barts Health. For the last 13 years, I’ve also had a personal research programme of looking at the development of biotherapies for cancer. There is no primary care in China, so research outside the hospital sector, whereas the majority of our patients in the CRN are recruited in primary care. Over the last few years, I’ve been given the opportunity to develop an academy of medical sciences approach across China’s Henan province, which has a population of 108 million people. We will be creating a network of specialties across China, and the aim is to join them up and create a framework with international standards of ethics and governance for conducting clinical research. It’s a fantastic opportunity to carry out research at scale and at pace, and to potentially look at rare diseases in a way that may be difficult, if not impossible, to do in smaller health economies. It’s a fascinating challenge.
Choices untangle contraception's web of confusion

Judith Stephenson, Margaret Pyke professor of sexual and reproductive health at UCL, on the research that has developed a user-friendly website to help guide women on how best to plan and prepare for pregnancy.

There are plenty of women who still think that their choice regarding contraception is between pills and condoms, when, in fact, there are lots of other methods.

One of the keys to the website is that it's interactive. Having entered information about herself, a woman can then click on “What's right for me?” and have three methods suggested that should suit her particular circumstances.

For the feasibility trial, we recruited women from all the settings where contraceptive consultations take place – sexual health clinics such as the Margaret Pyke Centre run by CNWL, general practice, the abortion service, maternity service and a community pharmacy. Initially, a researcher asked young women to get the website design colours and layout right.

“Whether you have a pregnancy, or not can profoundly affect you in many ways”

– Professor Judith Stephenson

In the text confirming their participation, we added a link and said: “Before your visit, please take a look at this website to take part in online contraception research.” The link would take her to the same page that would be seen by women being recruited face-to-face in clinic.

We recruited 530 women this way in six weeks, more than doubling the size of the trial. In total, we had 470 women who'd seen the website and 470 who hadn't. This meant that rather than doing a mini feasibility trial first, we could go straight to the big trial.

The first outcome we were interested in was whether seeing the website meant you were more likely to use a LARC method, and the second was to see how satisfied women were with whatever method they were using.

The comments were remarkably positive from women who'd seen the website, such as “I wish I'd seen this earlier”, and “It's made me think about changing to a more effective method of contraception.”

Despite the findings, we knew that the website had the potential to profoundly affect contraception choices on a much bigger scale.

The information on the website is important, but it's also about what your partner and peers think, other stories you've heard about it, and practical things such as whether you're able to get an appointment with a GP or a clinic to have a LARC method fitted.

The next step is to think about how the website could best be used in practice. The idea is that before attending a contraception consultation, a woman will

from reviewing a range of literature at the beginning of the study, that multiple factors come into play when deciding on contraception.

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Continued on next page >>

Making research everybody’s business
about how women prepare for pregnancy.

Whether you have a pregnancy or not, it can profoundly affect you in many ways – psychologically, emotionally, socially, culturally, and sometimes economically. So far, we have been studying how we can help in support of women, their partners, and their families. We have gathered data on the needs of pregnant and non-pregnant women and their families. We have set up for the women's health services to provide information on how women prepare for pregnancy.

In 2004, my UCL colleague Dr Geraldine Barrett developed a very useful pregnancy-planning tool called the London Measure of Unplanned Pregnancy – www.lmp.com. Instead of saying in black and white terms whether a pregnancy has occurred or not, the tool measures the extent of pre-pregnancy health. The first paper outlines why preconception health is important; the second is about how we can measure it; and the third lays out the kind of intervention strategies we need to improve preconception health.

Preconception wasn’t on people’s radar before, but it is now gaining traction and getting more attention. The first paper outlines why preconception health is important; the second is about how we can measure it; and the third lays out the kind of intervention strategies we need to improve preconception health.

The big gap in between doesn’t come under the scrutiny of the NHS. The likelihood is that at least half of pregnancies in the UK are planned to some degree – and two-thirds of those that lead to a live birth are planned – yet we know very little about how women prepare for pregnancy.

If a woman is a smoker, obese, has a mental health disorder or has high blood pressure, the risk of pregnancy complications and the health of the baby can increase. The bookends of pregnancy – the period just before you’re pregnant and the period just after – need a lot more attention.

In April 2018, we published three papers in the Lancet – http://bit.ly/2F3Ysj2 – to make the case for why we should be concentrating on these areas.

A paper by Public Health England, called Making the Case for Preconception Care – https://bit.ly/2IHpfGZ – came out in July 2018, and the study in London – led by chief investigator Dr Anita Lim, of the King’s College London Cancer Prevention Group, and funded by Cancer Research UK – will explore non-speculum alternatives, including both sampling by a clinician and self-sampling. Self-sampling is already offered in other countries, such as the Netherlands and Australia, enabling women to take a test themselves in private, at home, and without an appointment or examination.

Cervical screening tests using a speculum – the instrument used to hold open the walls of the vagina -- can be more uncomfortable for older and post-menopausal women.

Some women may also choose not to be screened because of embarrassment, busy lifestyles, and religious or cultural reasons.

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Underscreened women are at highest risk of developing cervical cancer hence the need to make screening for HPV – the virus that can cause cancer if left untreated – as acceptable and accessible as possible to all women.

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Q&A: Martin McKee, professor of European public health at the London School of Hygiene and Tropical Medicine, adviser to the EC on health and a member of Scientists for EU, outlines fears about Brexit effects on NHS research

Q. What impact will Brexit have on health research in the UK?

A. There is a lot of uncertainty – we have no idea what’s going to happen because the prime minister also has no idea – but to do world-class research you need to have world-class researchers. It’s going to become much more difficult for leading universities to recruit class researchers. It’s going to become much more difficult for leading universities to recruit internationally, and the proposed salary threshold could deter young people. Some researchers are looking to move away from the UK to Ireland or the Netherlands in particular and some have already moved. People are much less willing to apply for posts.

The most immediate problem is going to be our ability to recruit and retain researchers as the UK is increasingly becoming an unwelcoming place to work. This is unsurprising because, until recently, the UK has been explicit government policy to create a hostile environment to migrants.

Brexit would also lead to a vast increase in bureaucracy for those who want to come to work here, such as applying for settled status, applying for work permits. That will create a barrier that people don’t face elsewhere within the EU.

The potential consequences for family life are profound.

Q. How will funding for research be affected?

A. As a result, Brexit would mean we will be entirely cut off from all EU funding. If there is a deal, the best we can hope for is that we will continue to participate in the EU research and innovation programme Horizon 2020, but we would probably be excluded from the Erasmus+ student exchange programme, and would definitely be excluded from European Research Council funding.

The ability to participate in the networks will also be a problem. I’m currently involved in a Horizon 2020 bid that has got through to the second round, but because of the uncertainty, I am likely to participate through one of my affiliations in continental Europe, rather than the UK. And of course, the UK will not be able to lead these types of projects.

Q. What difference will Brexit make to patient care?

A. The immediate consequence is going to be access to medicines. In the last few months, we’ve realised how precarious the complicated pharmaceutical supply chain system is even at the best of times. Medicine shortages are much more problematic than food shortages – if you don’t get any concrete information.

A no-deal Brexit would mean we will be 100% dependent on the pharmaceutical supply chain, and would be hit. We’ve already seen that the economy has shrunk even more.

As Caroline Lucas MP has pointed out, the government has given the contract for control of the shipping routes to DHL, the company responsible for failing to deliver chicken to KFC restaurants last year, which doesn’t inspire a great deal of confidence.

Q. How will it impact your work?

A. It will be much more difficult for us to continue European collaborations, and delays at borders will make travelling to meetings on the continent much more complicated.

Q. Has Brexit affected the goodwill between the UK and European researchers?

A. Our European colleagues realise that the UK government has given the contract for control of the shipping routes to DHL, which has pointed out the enormous damage that has been done to our international reputation. They find it incomprehensible.

Brexit is universally bad for health and for the NHS. There is no good side to it whatsoever.

– Professor Martin McKee

Making research everybody’s business
A bold initiative developed at the East London NHS Foundation Trust has enabled mental health service users to carry out research into the benefits of People Participation (PP) teams – while improving their own health and well-being at the same time.

The PRIDE (Participation, Engagement, Involvement, Recovery and Experience) project, funded by a grant from the Centre for Public Engagement at Queen Mary University of London, adopted a novel approach that goes way beyond the usual involvement of service users in research. Normally, they would be involved in an advisory capacity or as additional members of professional researchers. Instead, PRIDE recruited a group of 15 service users – each with a least one year’s experience of being involved in a PP team – to develop the project’s design, materials and methods through workshops.

Three were then trained to manage day-to-day activities, carry out research interviews, analyse the data and author a peer-reviewed paper, with the support of experienced professional researchers. The project findings showed that PP initiatives can really benefit some patients and help their recovery through a positive effect on self-confidence, feeling valued, obtaining or refreshing personal skills, overcoming personal fears, and developing better ways to cope with their mental health problems.

I set myself boundaries because I guess we all live in our own safety nets when you have a mental illness,” said one participant. “PP actually makes me go to the edge, and sometimes over. And when I do that, I feel like, ‘Wow, I’m so glad I did that! I can really do that, you know.’

Positive feedback from participants often focused on a desire to “give something back”. As one said: “I felt a sort of passion in wanting to help improve things. I felt sort of a need to pay back some of the really great professionals I met across the years who’d helped me out.”

Another said: “It’s helped me because it’s made me think about what are the good things in life, what are the bad things, and what’s going to keep me well and safe and keep me from going back to hospital again.”

Participants also suggested that moving on support systems – i.e. getting their advice – should be part of PP programmes to help people who have engaged in and benefited from such involvement to progress to the next step by pursuing their goals in terms of employment and social inclusion.

The benefits indicated by PRIDE lend weight to the case for larger-scale studies on further initiatives can really benefit people who have engaged in and benefited from such involvement to progress to the next step by pursuing their goals in terms of employment and social inclusion.

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Pathways to training opportunities

The following sessions are being hosted by Noclor and our associates. All the sessions are free and open to all staff who have an interest in research (including doctors, dentists, nurses, research assistants) and who are working in, or are associated with, our partner trusts.

To register or find out further information about our free training sessions, please visit our Eventbrite page via: www.noclor.nhs.uk/training-resources

All our training sessions are advertised on our Eventbrite page.

Service users earn pride of place in PP research

RESEARCH RAISES NEW HOPE OF TREATING MEMORY LOSS

The development of new therapeutic molecules by Canadian researchers at Toronto’s Centre for Addiction and Mental Health shows great promise in reversing the memory loss linked to depression and ageing.

The molecules not only rapidly improve symptoms, but also appear to renew the underlying brain impairments causing memory loss. Although the medication has so far been tested only on mice, the positive results mean that plans are being developed to trial it with people with depression, and then with older patients.

Dr Etienne Sibille, the lead researcher, says developing medications to deal with these issues has been notoriously difficult. However, he believes the new drug could be administered as a pill to anyone in their late 50s at risk of cognitive problems in old age.
Projects currently recruiting

● **THRIVE**
A virtual reality (VR) treatment trial aiming to help build the confidence of people who have a persecutory delusion and feel threatened when with other people. Using VR to replicate real scenarios, the goal is for patients to be able to cope with entering feared situations, and transfer the learning to everyday life.

contact.noclor@nhs.net

● **GLAD**
Recruitment of at least 40,000 patients via GP practices to help towards creating the largest recontactable biobank of participants diagnosed with depression and anxiety, the two most common psychiatric disorders worldwide. The aim is to help develop better treatments by exploring genetic and environmental factors associated with risk of the disorders.

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Key Contacts

The Noclor Research Support team is here to help you with research. So please feel free to contact our various teams.

For queries relating to Research Management and Support: contact.noclor@nhs.net

Funding and Finance queries: finance.noclor@nhs.net

Looking for advice with or interested in a project in Primary Care? Contact: primarycare.noclor@nhs.net

Keen to learn more about our free training courses, or to offer content suggestions for future Noclor publicity material? Contact: irina.grinkova@nhs.net

If you would like to get in touch with our Service Director, Lynis Lewis, please contact: irina.grinkova@nhs.net

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Editorial content:
David Clare & Katie Shimmon

This paper is Forest Stewardship Council certified